REMARKS

Amendments to the Claims

Claims 48, 50, 53-55, 57-60, 62, 69, 70, 73 and 75 are pending. The Applicants respectfully ask the Examiner to replace all prior versions and listings of claims in the present application with the listing of claims currently provided. Claims 48, 50, and 57-60 were amended; Claims 104 and 105 are new. The Applicants hereby state that all amendments do not add new subject matter to the specification.

Claim 48 and 50 amendment support directed towards a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 that is a SNAP-25b variant having at least 80% identity to SEQ ID NO: 42 can be found throughout the present specification, such as, *e.g.*, p. 19, line 28 though p. 20, line 6; and FIG. 8.

Claim 48 and 50 amendment support directed towards a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 that is a SNAP-25b capable of supporting Ca^{2+}-mediated exocytosis can be found throughout the present specification, such as, *e.g.*, p. 12, line 17 though p. 13, line 23.

Support for Claims 104 and 105 can be found throughout the present specification, such as, *e.g.*, p. 20, lines 13-18; and p. 23, lines 1-5.

Amendment to the Sequence Listing Pursuant to 37 C.F.R. §§ 1.821-1.825

The Sequence Listing was amended in order to comply under 37 C.F.R. §§ 1.821-1.825 because each sequence disclosed in the specification did not appear in the Sequence Listing. The Applicant has submitted an amended copy of the computer readable form (CRF) of the Sequence Listing and the written Sequence Listing. The Sequence Listing information recorded in CRF is identical to the written Sequence Listing. The Sequence Listing provided does not contain any new matter as required by 37 C.F.R. §§ 1.821(e), 1.821(f), 1.821(g) and 1.825 (b).

Rejection Pursuant to 35 U.S.C. § 112, ¶ 1 Written Description

The Examiner has rejected Claims 48, 50, 53-55, 57-60, 62, 69, 70, 73, and 75 as allegedly failing to comply with the written description requirement under 35 U.S.C. § 112, ¶ 1. Specifically, the Examiner contends that the specification fails to teach any structural limitations of SNAP-25. The Applicants respectfully ask for reconsideration pursuant to 37 C.F.R. § 1.111.

Presently amended Claims 48 and 50 are directed, in part, towards a toxin-resistant SNAP-25 or a toxin-inhibitory SNAP-25 that is a SNAP-25b variant having at least 80% identity to SEQ ID NO: 42. Therefore, the Applicants submit that the present specification provides adequate written description support for all claims and respectfully request withdrawal of the 35 U.S.C. § 112, ¶ 1 written description rejection against Claims 48, 50, 53-55, 57-60, 62, 69, 70, 73, and 75.

Rejection Pursuant to 35 U.S.C. § 112, ¶ 2 Indefiniteness

The Examiner has rejected Claims 48, 50, 53-55, 57-60, 62, 69-70, 73 and 75 as allegedly being indefinite under 35 U.S.C. § 112, ¶ 2 because the term “substantially” is a relative term which renders the claim indefinite. The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.111.

The Applicants have amended Claims 48 and 50 and deleted the term “substantially.” Therefore, the Applicants respectfully submit that the presently amended claims are definite and respectfully request withdrawal of 35 U.S.C. § 112, ¶ 2 definite rejection against Claims 48, 50, 53-55, 57-60, 62, 69-70, 73 and 75.

Rejection Pursuant to 35 U.S.C. § 102(b) Anticipation

I. Anticipation rejections by Carroll.

The Examiner has rejected Claims 48, 50, 53-55, 57-60, 62, 69 and 70 as allegedly being anticipated under 35 U.S.C. § 102(b) by Sean B. Carroll et al., *Therapy for Clostridial Botulinum Toxin*, U.S. Patent 5,599,539 (Feb. 4, 1997), hereafter the "Carroll patent." As a basis for the anticipation rejections presently raised against the pending claims, the Examiner argues that the specification teaches that the term "SNAP-25" means any protein and cites the present specification at pg. 19, lines 15-27. See, April 10, 2007 Office Action at pg. 5, ¶ 4, lines 5-6. The Examiner contends that the Carroll patent anticipates on the ground that the disclosure inherently teaches the presently claimed methods "because SNAP-25 is a variant as described in the specification with insertions, deletions and substitutions and would also inherently be capable of performing substantially the equivalent function of a SNAP-25 in the absence of evidenced to the contrary." See, April 10, 2007 Office Action at pg. 6, ¶ 2, lines 11-14. The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.111.

According to *MPEP* § 2131, for a reference to anticipated a pending claim, that reference must teach each and every element of the pending claim.

Presently amended Claims 48 and 50 are directed, in part, towards a toxin-resistant SNAP-25 that is a SNAP-25b variant having at least 80% identity to SEQ ID NO: 42 that is capable of supporting Ca^{2+}-mediated exocytosis, but resistant to proteolysis by the clostridial toxin or a toxin-inhibitory SNAP-25 that is a SNAP-25b variant having at least 80% identity to SEQ ID NO: 42 that is capable of supporting Ca^{2+}-mediated exocytosis, but further capable of inhibiting the protease activity of the clostridial toxin.

The Carroll patent discloses methods of "treating humans and animals intoxicated with a bacterial toxin by oral administration of antitoxin raised against the toxin." See, col. 3, lines 27-29; and col. 4, lines 21-23. The Carroll patent indicates that a preferred toxin includes BoNT/A, BoNT/B, BoNT/C1, BoNT/D, BoNT/E, BoNT/F, and BoNT/G. See, col. 4, lines 45-

47; and Table 1. The antitoxin antibodies are obtained through immunization of mammals or non-mammals using an antigen. See. col. 4, lines 26-36; and Example s 1 & 3. Thus, the Carroll patent discloses methods of treating poisoning by a clostridial toxin in a patient by administering anti-clostridial toxin antibodies to a patient in need thereof.

Thus, the anti-clostridial neurotoxin antibodies disclosed in the Carroll patent do not anticipate presently claimed methods because anti-clostridial neurotoxin antibodies do not have at least 80% identify to SEQ ID NO: 42, are incapable of supporting Ca^{2+}-mediated exocytosis, and are incapable of inhibiting the protease activity of the clostridial toxin. Therefore, the Applicants respectfully submit that this rejection is unsupported and request withdrawal of the 35 U.S.C. § 102(b) anticipation rejection for Claims 48, 50, 53-55, 57-62, 69 and 70.

II. Anticipation rejections by Roland.

The Examiner has rejected Claims 48, 53, 57-60, 62 and 69 as allegedly being anticipated under 35 U.S.C. § 102(b) by Elke H. Roland et al., *Infant Botulism: A Rare Entity in Canada?*, 135(2) CMAJ 130-131 (1986), hereafter the "Roland reference." As a basis for the anticipation rejection presently raised against the pending claims, the Examiner argues that the specification teaches that the term "SNAP-25" means any protein and cites the present specification at pg. 19, lines 15-27. See, April 10, 2007 Office Action at pg. 8, ¶ 4, lines 5-6. The Examiner contends that the Roland reference anticipates on the ground that the disclosure inherently teaches the presently claimed methods "because SNAP-25 is a variant as described in the specification with insertions, deletions and substitutions and would also inherently be capable of performing substantially the equivalent function of a SNAP-25 in the absence of evidenced to the contrary." See, April 10, 2007 Office Action at pg. 9, ¶ 1, lines 11-14. The Applicants respectfully ask for reconsideration under 37 C.F.R. § 1.111.

According to *MPEP* § 2131, for a reference to anticipated a pending claim, that reference must teach each and every element of the pending claim.

Presently amended Claims 48 and 50 are directed, in part, towards a toxin-resistant SNAP-25 that is a SNAP-25b variant having at least 80% identity to SEQ ID NO: 42 that is capable of supporting Ca^{2+}-mediated exocytosis, but resistant to proteolysis by the clostridial toxin or a toxin-inhibitory SNAP-25 that is a SNAP-25b variant having at least 80% identity to SEQ ID NO: 42 that is capable of supporting Ca^{2+}-mediated exocytosis, but further capable of inhibiting the protease activity of the clostridial toxin.

The Roland reference discusses the case history of an infant diagnosed with botulism. Initially believing the infant had an infection, health care providers administered the patient ampicillin and gentamicin. See pg. 130, col. 1, ¶ 1, lines 3-7. However, 20 minutes after administering the antibiotics, the infant's condition worsen and assisted ventilation was required. See pg. 130, col. 1, ¶ 1, lines 7-9. Subsequently, examination of stool samples revealed the presence of BoNT/A bacteria and toxin and a diagnosis of infant botulism was made. See pg. 130, col. 2, ¶ 2, lines 1-7. The Roland reference indicated that the infant slowly recovered over two months with supportive treatment. See pg. 130, col. 2, ¶ 2, lines 7-8.

Thus, the ampicillin and gentamicin disclosed in the Roland reference do not anticipate presently claimed methods because these antibiotics do not have at least 80% identify to SEQ ID NO: 42, are incapable of supporting Ca^{2+}-mediated exocytosis, and are incapable of inhibiting the protease activity of the clostridial toxin. Therefore, the Applicants respectfully submit that this rejection is unsupported and request withdrawal of the 35 U.S.C. § 102(b) anticipation rejection for Claims 48, 53, 57-60, 62 and 69.

CONCLUSION

For the above reasons the Applicants respectfully submit that the claims are in condition for allowance, and the Applicants respectfully urge the Examiner to issue a Notice to that effect. The Examiner is invited to call the undersigned agent if there are any questions. Please use Deposit Account 01-0885 for the payment of any extension of time fees under 37 C.F.R. § 1.136 or any other fees due in connection with the current response.

Respectfully submitted,

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